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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,877	09/16/2003	Richard J. Whitbourne	32286-191984	1150

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
02/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,877	WHITBOURNE ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47 and 49-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47 and 49-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 4, 15-17, 20-22, 24-27, 29, 35-38, 49-57, and 59-61 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as

obvious over Zhong (6,197,051). Under U.S.C. 102(e): Zhong discloses, at least in col. 3, lines 15-24; col. 5, lines 5-40; col. 6, line 32 to col. 7, line 6; col. 7, lines 25-65; and col. 9, line 54 to col. 10, line 18; a stent or stent body having a coating including a primer layer having a polymer composition of two or more polymers (polycarbonate and polyurethane, which form the polycarbonate-polyurethane polymer, and at least one emulsifying agent) and a single outer most drug reservoir layer having a hybrid polymer composition of two or more polymers (polycarbonate-polyurethane with an organic acid functional group and a polyfunctional cross-linking agent) or a polymeric alloy; i.e., a toughening polymer or a hybrid polymer matrix, and comprising a drug stabilizing polymer (e.g., polyurethane) comprising one or more active agents as claimed, where the primer layer composition is distinct from the drug reservoir layer polymer composition, and where the primer layer is a single layer, where the primer layer comprises a polycarbonate urethane or an anchoring polymer, where the coating remains intact upon insertion and stent expansion, and where the active agent is alloyed with and deposited throughout the polymer composition.

Arguably, however, Zhong's polycarbonate-polyurethane polymer may not be considered a "polymer composition of two or more polymers" or a "polymeric alloy." Nevertheless and alternatively under 35 U.S.C. 103: Zhong teaches, in col. 9, lines 15-45; that the layers of the stent coating may comprise "combinations of one or more [separate] polymers and/or one or more non-polymers," where the polymers may include both "degradable and non-degradable polymers," their "copolymers," and "combinations" or "mixtures thereof." Zhong also lists known polymers, hydrophobic

and hydrophilic polymers, which include polymers as disclosed by the Applicant. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select known polymers, or alloys thereof, for the layers of Zhong's stent on the basis of their suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Also, with respect to claims 16, 21, 22, 27, 38, and 53-56 specifically, Zhong discloses the invention substantially as claimed, but does not disclose that one or more polymers have the mechanical properties as claimed, the total coating or layer thickness as claimed, and the blends of active agents as claimed. Nevertheless, Zhong teaches, in col. 8, lines 10-13, that "it is within the knowledge of one skilled in the art...to calculate appropriate bio-active agent concentrations for use in accordance with the present [Zhong's] invention." Thus, it would also be a matter of obvious design choice regarding polymers having the mechanical properties as claimed and the coating or layer thicknesses as claimed. The choices would be dependent upon the desired dosage of the drug or agent and time for the release of the drug or agent to the patient's body. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply active agents, or blends thereof, since selecting known materials on the basis of their suitability of the intended use as a matter of obvious design choice.

4. Claims 2, 5, 14, 23, 30, 47, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (6,197,051) in view of Fearnot et al. Zhong discloses the invention substantially as claimed, but does not disclose an intermediate layer or a

means for containing and controllably releasing an agent and comprising a stabilizing polymer and a toughening polymer as means for stabilizing the active agent and a means for strengthening the containing means, respectively, between the primer layer or a means for anchoring a containing means to a stent body and a single outermost drug reservoir layer, where the anchoring polymer has a functional group as claimed, where the intermediate layer comprises one or more polymers as claimed, where the intermediate layer has a thickness as claimed, where the intermediate layer comprises polycarbonate polyurethane, where the primer layer includes at least one hydrophobic polymer and at least one hydrophilic polymer and an anchoring polymer as claimed, and where the single outermost drug reservoir layer includes at least one hydrophobic polymer and at least one hydrophilic polymer, a drug stabilizing polymer, and a toughening polymer. Fearnot teaches, at least in figures 4 and 5 and in col. 3, lines 17-23 and col. 4 lines 16-22; a stent body (12) including an intermediate layer (14) or a means for containing and controllably releasing an agent and comprising a stabilizing polymer and a toughening polymer as means for stabilizing the active agent and a means for strengthening the containing means, respectively, between the primer layer or a means for anchoring a containing means to the stent body and a single outermost drug reservoir layer, where the anchoring polymer has a functional group as claimed, where the intermediate layer comprises one or more polymers as claimed, where the intermediate layer has a thickness as claimed, where the intermediate layer comprises polycarbonate polyurethane, where the primer layer includes at least one hydrophobic polymer and at least one hydrophilic polymer and an anchoring polymer as claimed, and

where the single outermost drug reservoir layer includes at least one hydrophobic polymer and at least one hydrophilic polymer, a drug stabilizing polymer, and a toughening polymer, where the abovementioned polymers comprise a group consisting of cellulose acetate, cellulose nitrate, polyethylene teraphthalate, polyurethane, polyamide, polyester, polyorthoester, and polyanhydride; while Zhong teaches polycarbonate polyurethane or a combination of polymers as a hybrid polymer. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply an intermediate layer or a means for containing and controllably releasing an agent on the stent body of Zhong. Such a layer would allow the controlled release of at least one drug or agent working in concert with the at least one drug or agent released from the outermost layer. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply and blend polymers as claimed for the primer, the intermediate layer or the means for containing and controllably releasing an agent, and the drug reservoir layer, since selecting known materials on the basis of their suitability of the intended use as a matter of obvious design choice. It would also be a matter of obvious design choice regarding the coating thickness of the intermediate layer. The choice of coating thickness would be dependent upon the desired dosage of the drug or agent and time for the release of the drug or agent to the patient's body.

5. Claims 3, 6-13, 18, 19, 28, 31-34, and 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (6,197,051) in view of Pacetti et al. (6,663,662). Zhong discloses the invention substantially as claimed. Zhong discloses a stent having

a primer layer and a single outermost drug reservoir layer comprising modifications of polycarbonate-polyurethane and active agents. However, Zhong does not disclose that the stent includes one or more image enhancing materials, nor does Zhong discloses that the layers comprise the polymers as claimed, or blends thereof, and that the agents include the specific agents as claimed. Pacetti et al. teach, at least in col. 4, line 51 to col. 6, line 44; col. 8, lines 13-43 (Table 1); col. 10, line 63 to col. 11, line 50; col. 11, line 66 to col. 12 line 57; col. 13, lines 8-25; and col. 14, lines 15-23; a stent including one or more image enhancing materials (e.g., metallic particles) and polymeric layers comprising polymers as claimed, and blends thereof, as well as agents as claimed. However, Zhong and Pacetti do not disclose or teach the trademarked polymers and epoxies as claimed. Nonetheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include image enhancing materials in at least one of the layers in the stent of Zhong. Such materials, such as metallic particles, would not only aid in visualization of the stent and its location within a patient's body, they would allow the controlled release of active agents into the body. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply and blend polymers and epoxies as claimed for the primer layer and the drug reservoir layer and to apply active agents as claimed, since selecting known materials on the basis of their suitability of the intended use as a matter of obvious design choice.

Response to Amendment

6. Applicant's arguments with respect to rejections of claims 1-47 and 49-61 and based on the Zhong reference have been considered but are not persuasive. That is, Zhong indeed discloses a distinct, single outermost drug reservoir layer comprising two polymers (polycarbonate and polyurethane) and used to release bio-active agents over a sustained period. Even if one considers "polycarbonate-polyurethane polymer" a "single polymer," as the Applicant posits," the polymer comprises or includes distinct polycarbonate and polyurethane polymers combined together, at least chemically bound together, which would still fall under the purview of a "polymer composition comprising a polymeric alloy of two or more polymers." In other words, the claims do not require "two or more separate polymers" as argued by the Applicant. Applicant is reminded that it is the language itself of the claims which must particularly point out and distinctly claim the subject matter which the Applicant regards as the invention, without limitations imported from the specification, whether such language is couched in terms of means plus function or consists of a detailed recitation of the inventive matter. Limitations in the specification not included in the claim may not be relied upon to impart patentability to an otherwise unpatentable claim. In re Lundberg, 113 USPQ 530 (CCPA 1957). In any case and as shown in the rejection above, it would be obvious to one having ordinary skill in the art, in view of Zhong, to apply a polymeric alloy of two or more separate polymers in the outermost drug reservoir layer.

Regarding the Applicant's argument that Zhong's bioactive agents are covalently bonded to a polymeric coating and cannot be eluted from the coating: The Examiner

respectfully disagrees. Zhong suggests, at least in col. 1, line 64 to col. 2, line 33; that like prior-art endoprostheses, the outermost layer of Zhong's device contains bio-active agents "anchored for controlled delivery thereof over time." Covalently bonding of bio-active agents to a polymeric coating serves to "enhance the biostability, abrasion-resistance, lubricity, and bio-activity of the surface of implantable medical devices" (col. 2, lines 33-45. Covalent bonding does not prevent elution of bio-active agents. Moreover, Zhong teaches, in col. 7, line 66 to col. 8, line 45; that some bio-active agents may become "lubricious upon contact with an aqueous medium." This action or wetting of bio-active agents suggests dissolving, elution, and activation of bio-active agents from a stent coating. Additionally, "degradable" polymers may be applied in a stent coating, and upon degradation of the polymers in a patient's body, bio-active agents would inherently be released or eluted from the coating. Also, Zhong teaches, at least in col. 6 lines 58 to col. 7, line 12 and col. 10, lines 19-51; the application of an "internal emulsifying agent" that covalently bonds a bio-active agent to a polymer coating, yet allows enhanced bio-activity of the coating, i.e., the release of or elution of the bio-active agent.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773